USDA

United States
Department of
Agriculture

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

510 S. 17th Street,
Suite 104
Ames, IA 50010
(515) 232-5785
FAX (515) 232-7120

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 06-02

Subject: Issuance of a Conditional License for Avian Influenza Virus
Type A Antigen Test Kit

To: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics
Area Veterinarians in Charge, VS
State Veterinarians

The Animal and Plant Health Inspection Service (APHIS) has issued a conditional
United States Veterinary Biological Product License to Synbiotics Corporation,
Establishment No. 312, San Diego, California, for the manufacture and distribution
of Avian Influenza Virus Type A Antigen Test Kit.

A veterinary biological product regulated under the Virus-Serum-Toxin Act must be
shown to be pure, safe, potent, and efficacious before a veterinary biological product
may be issued. The regulations in 9 CFR Part 102 regarding the licensing of biological
products provide that a conditional veterinary biological product license may be issued
to meet an emergency situation, limited market, local situation, or other special
circumstances. There is no licensed diagnostic test kit currently available that provides
a rapid *in vitro* assay for the detection of avian influenza virus antigen in specimens
derived from tracheal and cloacal origin.

This conditional license was issued following the acceptance of data demonstrating
adequate kit performance for the detection of avian influenza antigen in clinical
specimens and experimentally prepared specimens. The firm is required to collect
additional field data and further validate the diagnostic specificity and sensitivity of
this kit before APHIS will issue a regular product license. The conditional license
will expire in one year.

/s/ Byron E. Rippke for

Richard E. Hill, Jr.
Director

APHIS *Safeguarding American Agriculture*
APHIS is an agency of USDA's Marketing and Regulatory Programs

An Equal Opportunity Provider and Employer

Federal Relay Service
(Voice/TTY/ASCII/Spanish)
1-800-877-8339